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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,909	11/23/2001	George Jackowski	2132.090	7376

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT PAPER NUMBER

1646

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,909

Applicant(s)

JACKOWSKI ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) 39-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 29, 2004 has been entered.

Response to Amendment

2. Claim 1 has been amended as requested in the amendment filed on November 29, 2004. Claims 1 and 39-46 are pending in the instant application.

Claims 39-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made by original presentation in Paper mailed on May 28, 2004.

Claim 1 is under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on November 29, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated peptide, designated a “biopolymer marker”. The instant application does not disclose a specific biological role for this peptide or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

It is clear from the instant application that the protein described therein is a fragment of a larger molecule, complement C3 precursor protein, which has been isolated because of potential association of complement C3 precursor protein with Alzheimer’s disease. There is little doubt that, after complete characterization, this peptide consisting of amino acid residues 2-14 of SEQ ID NO: 1 may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant’s claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are “useful” as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed “real world” utility. The court held that:

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“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility”, “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field”, and “a patent is not a hunting license”, “[i]t is not a reward for the search, but compensation for its successful conclusion”.

The nature of the invention is the finding of specific fragments of complement C3 precursor protein, which are polypeptides of SEQ ID NO: 1-4 and which are asserted to be associated with Alzheimer’s disease, in a serum sample treated according to a protocol provided on pages 40-46 of the instant specification. It is further stated on page 46, last paragraph and page 47, first paragraph of the instant specification, as filed, that “Figures 1 and 4 are photographs of a gel which is indicative of the presence/absence of the marker in disease vs. control and, in cases where the marker is always present, the relative strength, e.g. the up or down regulation of the marker relative to categorization of disease state is deduced”. However, the instant specification fails to provide any evidence or sound scientific reasoning that the instant claimed peptide consisting of amino acid residues 2-14 of SEQ ID NO: 1 is associated with any pathological condition, including Alzheimer’s disease. Based on the limited information on how to conduct mass spectrometric analysis of a sample presented in the instant specification and on the analysis of Figures 1 and 4, one skilled in the art clearly would not be able to use the polypeptide of SEQ ID NO: 1 as a biopolymer marker for any disease.

Furthermore, the instant specification fails to explain either a biological significance of the claimed biopolymer marker in the development of Alzheimer’s disease or the relationship between a polypeptide of SEQ ID NO: 1 and “particular disease state”. While it is not necessary

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that Applicant understands or discloses the mechanism by which the invention functions, in this case, in the absence of such an understanding the following questions must be answered. Is it “the up or down regulation of the marker relative to categorization of disease state”? Or is “the presence/absence” of the peptide consisting of amino acid residues 2-14 of SEQ ID NO: 1 indicative of a disease? Because this critical information is not provided in the instant specification, as filed, a skilled practitioner would have to first use the claimed biopolymer marker as the object of future research to establish the specific and substantial credible utility of the claimed peptide. However, it is a matter of law that the claimed invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention.

At page 11 of the Response, Applicant submits that claim 1 was amended to include recitation “linked to Alzheimer’s disease”. There appears to be no such recitation within the text of the claim, as presented in the amendment filed on November 28, 2004.

Applicant further submits that “the marker sequence being amino acid residues 2-14 of SEQ ID NO: 1 which evidences a link to Alzheimer’s disease. All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art” (middle at page 12 of the Response). Applicant’s arguments have been fully considered but are not persuasive for the following reasons.

A specification can meet the legal requirements of utility and enablement for a new peptide as long as the specification discloses at least one credible, specific and substantial asserted utility for the new peptide, or a well-established utility for the claimed peptide would be immediately obvious to the skilled artisan. A hypothetical example may serve to clarify. For

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example, a hypothetical specification discloses that a claimed peptide is expressed in colon cancer and not expressed in healthy colon tissue. The hypothetical specification does not disclose the biological activity of the polypeptide encoded by the peptide. The claimed peptide in the hypothetical example would not be rejected under 35 U.S.C. §§ 101 and 112, first paragraph, as it has utility and is enabled as a colon cancer marker. However, such is not the fact pattern here. For example, the text on page 11, third paragraph, states that “a biopolymer marker which is strongly present in a normal individual, but is down-regulated in disease is predictive of said disease; while alternatively, a biopolymer marker which is strongly present in a disease state, but is down-regulated in normal individuals, is indicative of said disease state”. Based on this information, a skilled artisan would have to resort to substantial amount of further research in order to discover how to use the claimed biopolymer marker of SEQ ID NO: 1 in diagnosis of Alzheimer’s disease, for example.

Applicant further argues that “[w]hen a peptide is identified in a body fluid sample from an Alzheimer’s patient, it is immediately recognized as a potential diagnostic marker, even if the involvement of the peptide in the pathology of Alzheimer’s disease is unknown” (last paragraph at page 13 of the Response). The Examiner agrees that in order to serve as a marker, a biological role of the peptide does not have to be disclosed. However, while not required by any statute or rule, if Applicant had disclosed a biological role or function of the claimed peptides, such might support a disclosed utility, such as for diagnosis of a disease. However, no such role has been disclosed. This alone is not probative of lack of utility under 35 U.S.C. § 101, but is merely one of the analyses, which must be made. If there were another specific, substantial and credible utility disclosed for the claimed biopolymer marker consisting of amino acid residues 2-14 of

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SEQ ID NO: 1, that would, in the absence of any knowledge of the biological function or role of the claimed peptide molecules, be sufficient to establish utility.

Regarding the merit of the argument, the Examiner maintains that, contrary to Applicant's statement, a proper biological marker is not the one that is "identified in a body fluid sample from an Alzheimer's patient" but rather the one that is also not found in a body fluid sample from a control patient free of Alzheimer's disease as well as from a patient suffering from another, not Alzheimer's, disease. Because the instant specification fails to present any evidence that would clearly support the specific substantial and credible utility of the claimed peptide as a marker for any disease, then to employ a peptide of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the isolated biopolymer marker consisting of amino acid residues 2-14 of SEQ ID NO: 1 in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility

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for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1646

January 19, 2005